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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,515	06/12/2001	Billy W. Colston	IL-10715	5330

7590 08/09/2004

Alan H. Thompson
Assistant Laboratory Counsel
Lawrence Livermore National Laboratory
P.O. Box 808, L-703
Livermore, CA 94551

[REDACTED] EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,515	COLSTON ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 May 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 and 36-43 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-8, and 36-43 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 12 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 5/10/2004 is acknowledged and entered. Claims 1-4, 7-8, and 36-43 have been amended.

2. Claim 9 was canceled by the amendment filed on 1/27/2004.

3. Claims 10-35 were canceled by the amendment filed on 10/02/2002. The filed amendment indicated that "*Non-elected Claims 10-35 have been cancelled without prejudice to the filing of a divisional application covering this claimed subject matter*" and "*Non-elected Claims 10-35 have been cancelled*". Therefore, claims 10-35 are cancelled not withdrawn as designated in the amendment filed 5/10/2004.

4. Claims 1-8, and 36-43 are pending.

5. Claims 1-8, and 36-43 are treated on the merit in this Office Action.

Withdrawn Rejections

6. The rejections of claims 1-8, and 36-43 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been withdrawn in light of applicant's amendments of claims 1-4, 7-8, and 36-43.

7. The rejection of claims 1-3, 5-6, 36 and 40 under 35 USC 102(b) as being anticipated by Pyle et al. (US Patent 5,821,066) has been withdrawn in light of applicant's arguments, and amendments of claims 1-3, 36, and 40.

8. The rejection of claims 1 and 8 under 35 USC 102(e) as being anticipated by Seul et al. (US Patent 6,387,707 B1) has been withdrawn in light of applicant's arguments, and amendments of claims 1, and 8.

9. The rejection of claims 41-43 under 35 USC 103(a) as being obvious over Pyle et al. (US Patent 5,821,066) and Nazareth et al. (US Patent 6,319,676 B1) has been withdrawn in view of applicant's arguments, and amendments of claims 41-43.

10. The rejection of claims 1 and 4 under 35 USC 103(a) as being obvious over Marshall (US Patent 5,236,826) and Okusa et al. (US Patent 4,952,520) has been withdrawn in view of applicant's arguments, and amendments of claim 1.

New Rejections

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-8, and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) The term “optically encoded microbead” of claims 1 and 41 is vague and indefinite because it is unclear what constitutes the metes and bounds of ‘optical encoding’ with regard to the step of adding fluorescent labeled antibodies. What is the distinction between a microbead with a tag such as a fluorescent label, microbead with a fluorescent coating, and a color microbead? If the “optically encoded microbead” is microbead with a fluorescent label, the method of claim 1 and 41 are confusing in that the step of adding fluorescent labeled antibodies follows the step of providing a multiplicity of optically encoded microbeads. Thus the term “optically encoded microbead” is vague and indefinite.
- b) The term “optically encoded microbead” of claims 1 and 41 is vague and indefinite because it is unclear what constitutes the metes and bounds of ‘optical encoding’ with regard to the optically decoding step. What is the distinction between a microbead with a tag such as a fluorescent label, microbead with a fluorescent coating, and a color microbead? If the “optically encoded microbead” is microbead with a fluorescent label and these microbead also have fluorescent labeled antibodies (i.e. the step of adding fluorescent labeled antibodies), the claim method of claim 1 and 41 is confusing as to what is being detected with regard to the optically decoding step (i.e. the fluorescent labeled antibodies or the fluorescent label of the microbead). Thus the term “optically encoded microbead” is vague and indefinite.

- c) Clarification is needed between the optically encoded microbeads with a capture ligand and the optically encoded microbeads with bioagent-specific antibodies in that are these microbeads the same microbeads since the specification discloses that the microbeads contain both capture ligand and bioagent-specific antibodies (pg. 11, paragraph [0038], lines 3-4; fig. 4).
- d) The method step of “providing said optically encoded microbeads with a capture ligand” is confusing in that it is unclear if each microbeads has a capture ligand or it is the type of capture ligand on the microbead.
- e) Claim 8 is confusing because it is unclear as to the relationship of the optically encoded microbeads with capture ligand of claim 1 and the optically encoded microbead with a substrate capture point. The specification discloses that the ‘capture ligand’ on the microbead is the ‘substrate capture point’ (pg. 11, paragraph [0038], lines 3-4, and 12-15; fig. 4 and 7C).
- f) Claim 36 is vague and indefinite because it is unclear what is an optically encoded optically encoded microbeads, charged optically encoded microbead, and optically encoded microbeads with optically encoded shells.

Allowable Subject Matter

13. The following is an examiner’s statement of reasons for allowance: The claimed optically encoded microbead containing both a capture ligand and bioagent-specific antibody use in the claimed method is not taught or suggested by the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
July 30, 2004



PADMASHRI PONNALURI
PRIMARY EXAMINER